

REMARKS

Status of the Claims

Claims 58, 60, 62-66, and 68-71 are allowed. Claims 59, 61 and 67 are pending and currently under consideration.

Rejections under 35 U.S.C. § 112, first paragraph

In the Office Action of August 8, 2005, claims 59, 61, and 67 are rejected under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the written description requirement. According to the Office, “[c]laims 59, 61 and 67 present a list of inflammatory diseases and conditions Applicant wishes to address. This is new matter as there is *no conception of the disorders* in the specification.” Office Action, p. 2. (emphasis added). The Advisory Action of March 22, 2006 states that “the section applicant directs to only supports treating the diseases using an isolated P-selectin ligand protein. There is no support for treating the diseases using the fusion protein comprising amino acid residues 42-60 of SEQ ID NO: 2, and a non-P selectin ligand amino acid sequence.” Advisory Action, p. 2.

The basis for rejection in the Office Action, alleged lack of conception of the disorders of the claims, differs from the rejection of the Advisory Action, alleged lack of support for the use of P-selectin ligand fusion proteins to treat the conditions of the claims. Nevertheless, the specification specifically describes treatment of the conditions enumerated in the claims using “P-selectin ligand protein”, and the specification

indicates that the term “P-selectin ligand protein” includes fusion proteins comprising amino acid residues 42-60 of SEQ ID NO: 2.

A. The Specification Supports the Use of P-selectin Ligand Fusion Proteins to Treat the Conditions of Claims 59, 61 and 67

There are at least three sources of support in the specification for the subject matter of claims 59, 61 and 67. First, the specification describes the use of P-selectin ligand proteins to treat the specific conditions enumerated in claims 59, 61 and 67. Second, the specification teaches that the term “P-selectin ligand protein” should be interpreted broadly to include “fusion proteins” such as those of claims 59, 61 and 67. Finally, the specification discloses a structure-function relationship between a specific region of a P-selectin ligand protein and the desired activity of binding to P-selectin. The written description requirement may be met if the specification discloses “functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (quoting Guidelines, 66 Fed. Reg. at 1106).

1. The diseases of claims 59, 61 and 67 are described in the specification

The specification supports claims to treatment of the conditions enumerated in claims 59, 61 and 67 as it specifically describes the treatment of these conditions using P-selectin ligand protein:

Isolated P-selectin ligand protein may be useful in treating conditions *characterized by P-, E- or L-selectin mediated intercellular adhesion*. Such conditions include, without limitation, myocardial infarction, bacterial or viral infection, metastatic conditions, inflammatory disorders such as arthritis, gout, uveitis, acute respiratory distress syndrome, asthma,

emphysema, delayed type hypersensitivity reaction, systemic lupus erythematosus, thermal injury such as burns or frostbite, autoimmune thyroiditis, experimental allergic encephalomyelitis, multiple sclerosis, multiple organ injury syndrome secondary to trauma, diabetes, Reynaud's syndrome, neutrophilic dermatosis (Sweet's syndrome), inflammatory bowel disease, Grave's disease, glomerulonephritis, gingivitis, periodontitis, hemolytic uremic syndrome, ulcerative colitis, Crohn's disease, necrotizing enterocolitis, granulocyte transfusion associated syndrome, cytokine-induced toxicity, and the like. . . . Isolated P-selectin ligand protein may be used to treat hemodialysis and leukophoresis patients. Additionally, isolated P-selectin ligand protein may be used as an antimetastatic agent. Isolated P-selectin ligand protein may be used itself as an inhibitor of P-, E- or L-selectin-mediated intercellular adhesion or to design inhibitors of P-, E- or L-selectin-mediated intercellular adhesion.

Specification, p. 21, line 34 to p. 22, line 19. (emphasis added). Thus, applicants clearly conceived of these diseases. Because this passage of the specification teaches that these conditions are “characterized by P-, E- or L-selectin mediated intercellular adhesion,” it suggests that proteins that retain P-selectin ligand protein activity could be used to treat these conditions. In fact, as discussed in detail below, the specification teaches that the term “P-selectin ligand protein” is defined in terms of protein activity, and includes fusion proteins. Accordingly, the passage of the specification recited above cannot be read to limit claims 59, 61 and 67 to the use of only full length proteins not fused to any other moiety, but should be understood more broadly to include the active P-selectin ligand fusion proteins of the claims.

2. The term “P-selectin ligand protein” encompasses fusion proteins

The specification states that “[f]or the purposes of the present invention, all references to ‘P-selectin ligand protein’ herein include fragments capable of binding to

P-selectin.” *Specification*, p. 13, lines 22-23. “Such fragments can fused to carrier molecules such as immunoglobulins.” *Specification*, p. 13, line 24. The specification makes clear that the segment of SEQ ID NO: 2 from amino acid 42 to amino acid 60, the subject of claims 59, 61 and 67, exhibits P-selectin activity. “In other embodiments, the present invention includes a P-selectin ligand protein having P-selectin ligand protein activity. In preferred embodiments, the ligand protein is a protein comprising the sequence from amino acid 42 to amino acid 60 of SEQ ID NO: 2. *Specification*, p. 5, line 25. The specification describes several working examples of truncation proteins that retain the ability to bind to P-selectin, including those bearing amino acids 42-60 of SEQ ID NO: 2. *Specification*, Example 10 E. The specification also describes fusion proteins comprising amino acids 42-60 of SEQ ID: NO: 2. “The present invention also provides a fusion protein comprising (a) a first amino acid sequence comprising amino acid 42 to amino acid 60 of SEQ ID NO: 2, and (b) a second amino acid sequence derived from the sequence of a protein other than P-selectin ligand.” *Specification*, p. 6, line 28. The specification includes working examples of P-selectin fusion proteins that include amino acids 42-60 of SEQ ID NO: 2. (Example 15). Thus, “P-selectin ligand protein” is defined broadly in the specification and includes the fusion proteins of claims 59, 61 and 67.

3. The specification discloses a structure-function relationship between P-selectin ligand protein and protein activity

The specification also supports claims 59, 61 and 67 as it discloses a structure-function relationship between the structure of P-selectin ligand protein and protein

activity. A disclosure of a correlation between structure and function can support a finding of adequate written description. *Enzo*, 323 F.3d 356. The specification discloses that segments of P-selectin ligand protein that exhibit protein activity include amino acids 42-60 of SEQ ID NO: 2. *Specification*, p. 5, line 25. Thus, the specification teaches that proteins comprising amino acids 42-60 of SEQ ID NO: 2 retain an activity that could block the selectin-mediated adherence that characterizes the conditions of claims 59, 61 and 67. One skilled in the art would have understood from the specification that proteins that comprise amino acids 42-60 of SEQ ID NO: 2 have the activity that is the basis for the invention, whether as isolated fragments or as part of a fusion protein. Accordingly, the disclosure of the specification would convey to one skilled in the art that Applicants were in possession of the invention.

CONCLUSION

The specification provides support for the subject matter of claims 59, 61 and 67 for at least three reasons 1) treatment of the conditions of claims 59, 61 and 67 using a P-selectin ligand protein is described in the specification; 2) the term “P-selectin ligand protein” is defined broadly to include proteins that retain activity, such as those that comprise amino acids 42-60 of SEQ ID NO: 2; and 3) the specification discloses a correlation between structure-function that would convey to one skilled in the art that the applicants were in possession of the subject matter of claims 59, 61 and 67.

In view of the foregoing remarks, Applicants submit that the claimed invention, is fully supported by the specification. Applicants therefore request the Examiner's

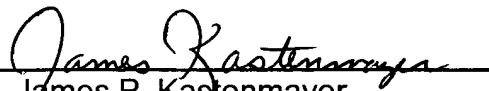
reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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